K 051077

MAY - 3 2005

Aseptico International

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510(k) Summary

Contact: Grant Ramaley

Date Prepared: April 11, 2005

Trade or Proprietary Name: AHP-101 E-Type Straight Handpiece

Classification Name: 872.4200 Dental Handpiece and Accessories

510(k) Number:

Device Description:

The AHP-101 is a straight, fully autoclavable, 1:1 ratio E-Type dental handpiece intended for use in general dentistry procedures. It accepts standard 2.35mm (3/32") burs and may be used with prophy angles.

Features of Substantial Equivalence to Aseptico's AHP-64 Handpiece [510(k) K020137]

1) Intended for general dentistry procedures
2) Fits all E-type dental handpiece motors
3) Fully autoclavable. Independently validated sterility assurance level (SAL) of 10^{-6}
4) Straight, 1:1 gear-ratio design
5) 0 - 30,000 RPM input speed range
6) Constructed of stainless steel, brass, and anodized aluminum
7) Complies with applicable portions of the following standards: ISO 7785-2:1995, ISO 3964:1982, ISO 11134:1994, AAMI TIR No. 12-1994

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 3 2005

Aseptico, Incorporated
C/O Mr. Daniel W. Lehtonen
Responsible Third Party Official
Intertek Testing Services NA, Incorporated
70 Codman Hill Road
Boxborough, Massachusetts 01719

Re: K051077
Trade/Device Name: AHP-101 E-Type Straight Handpiece
Regulation Number: 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EGS
Dated: April 25, 2005
Received: April 27, 2005

Dear Mr. Lehtonen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051077

Device Name: AHP-101 E-Type Straight Handpiece

Indications for Use:

The AHP-101 fully autoclavable, straight, 1:1 ratio E-Type dental handpiece is intended for use in general dentistry procedures, such as removing carious material from the dentine.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin Mulley for MSK

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K051077